K122/96



MAY 2 2013

### 510(k) Summary

1. Applicant Name:

Blackrock NeuroMed, LLC, 675 Arapeen Dr., Suite 105 Salt Lake City, UT 84108 Phone: 801.994.5662 Contact: Andy Gotshalk

2. Trade Name:

Cervello<sup>TM</sup> Bio-Potential Signal Acquisition System

3. Common Name:

Bio-Potential Signal Acquisition System

4. Manufacturing Site:

Blackrock NeuroMed, LLC 675 Arapeen Dr., Suite 105 Salt Lake City, UT 84108

Establishment Registration Number: 3007323246

5. Summary Date:

March 15, 2013

Classification Name: 21 CFR 882.1400 Electroencephalograph

Class II

Product Code: GWQ, OLV, GWL, GWK

Panel: Neurology

7. Reason for 510(k):

Consolidation/Modification of existing devices

8. Description:

Multi-Channel, Multi-Modal Physiological Monitoring System

Cervello Ambulatory – This system uses the Cervello Amplifier in the ambulatory environment and provides up to 64 input channels for EEG and PSG studies. The Amplifier is battery powered during recording; the internal microcontroller stores the data in a RAM buffer and memory card where it can be downloaded later for review by a physician.

Cervello Basic – This is a PC-based clinician-oriented EEG and/or PSG monitoring system that provides between up to 128 channels for EEG recording using the Cervello Amplifier. Data is displayed on a monitor using the Cervello Basic software program and video capabilities are available.

Cervello Elite — This is a PC-based clinician-oriented monitoring system that provides up to 256 channels for recording bio-potentials such as electroencephalography (EEG), electromyography (EMG), electroencephalography (ECG), electrocorticography (ECG) and evoked potential (EP) using the NeuroPort Bio-Potential System Hardware and operates both the Cervello (Basic) and the Central Software. Video capabilities are available.

In all cases, and as with the predicate devices, the Cervello Basic, Ambulatory and Elite Systems are not monitoring systems. No physiologic alarms are provided. The acquisition and display of bio-potential signals is for the interpretation and use of the clinician. The devices do not make any judgment of normality or abnormality of the displayed signals and the software is not intended to do automatic analysis of the recorded signals

9. The Company does not sell any of the following accessories: EEG electrodes, accessory cables, oximeter sensors, cannulae and respiratory effort sensors. Predicate Device(s):



510(k) Number:

K090957

Manufacture:

I2S Micro Implantable Systems, LLC d/b/a Blackrock Microsystems

Trade Name:

Blackrock NeuroPort Bio-potential Signal Processing System **GWL** 

Product Code: Classification:

882.1835

510(k) Number:

K071782

Manufacture:

Micromed S.P.A.

Trade Name:

Micromed Brain Spy Plus, Micromed Morpheus, Embla Titanium Devices

Product Code: Classification: GWQ 866.3740

510(k) Number:

K000963

Manufacture: Trade Name:

Airsep Corp. (Marketed by Embla) Da Vinchi EEG and EMG/EP Systems

Product Code:

GWQ 866.3740

Classification:

## 10. Intended Use of Device

Ambulatory- Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array and user-specified electrode locations.

Basic - Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array and user-specified electrode locations.

Elite- Acquire, amplify, record, display, digitize, retrieval, store and display bio-potential signals

#### 11. Indication for Use

The Blackrock NeuroMed Cervello Bio-Potential Signal Acquisition Product Family contains the following configurations.

Ambulatory: Up to 64 channels with one Cervello hardware device (Amplifier) using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG.

The Cervello Ambulatory system does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

Basic: Up to 64 channels with one Cervello hardware device (Amplifier) and up to 128 channels by cascading 2 Cervello devices using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG. The Cervello Basic system does not make any judgment of normality or abnormality of the displayed signals or the

results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

Elite: Up to 128 with one Neuroport Bio-Potential Recording Systems and up to 256 by cascading two Neuroport systems using the Central and/or Cervello software. The system supports recording, processing and display of biopotential signals from user-supplied electrodes. Bio-potential signals include: Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG), electrocculography (EOG) and Evoked Potential (EP). Intended users include Physicians, technicians, clinicians or other medical professionals that are trained in bio-potential and/or EEG recording.

The Cervello Elite system does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

### 12. Technological Characteristics



The hardware and software is very similar to other products on the market and does not differ significantly in any respect. This system combines the hardware and software platforms of the predicates and as such, it has identical technological characteristics. Software verification and validation and hardware-related performance testing was submitted in the predicate device applications, and the V&V/performance testing necessary to support the use of the Cervello software on the NeuroPort hardware was submitted with this application.

## Performance testing included:

- Third-party testing for compliance with IEC 60601
- Shipping Validation for both cart based systems (Elite and Basic) using the required packaging
- Internal testing to ensure the cart meets tipping requirements
- Additional Software Testing Documentation



13. Comparison to Predicates
A summary of the comparison table is shown below for the Cervello Elite, Basic and Ambulatory

		Table 4.0 Predicate Table Comparison - Elite	ble Comparison		
		Blackrock Neuroport Bio-potential Signal		-	
	<i>J</i>	Processing System	Micromed Morpheus, etc.	Airsep Corporation	Substantial Equivalence
Feature	Blackrock NeuroMed Ceryello Elite	(K090957)	(K071782)	(K000963)	Comments
Indications for	Up to 128 with one Neuroport Bio-	Supports recording, processing and display of	Acquire and store physiological	DA VINCHI EEG Systems are	Same/equivalent indications for
Use	Potential Recording Systems and up to	biopotential signals from user supplied	signals for EEG and Sleep	used for the acquisition, display	Use Therefore, Substantially
	256 by cascading two Neuroport	electrodes. Biopotential signals include:	Studies, and to transfer the data to	and storage of biologic signals	Equivalent,
	systems using the Central and/or	Electrocorticography (ECoG),	separate polysomnographic	relating principally to, cortical	
	Cervello software. The system	electroencephalography (EEG),	analysis software.	surface potentials with additional	•
	supports recording, processing and	electromyography (EMG),		capabilities of collecting	
	display of bio-potential signals from	electrocardiography (ECG),		polygraphic signals such as EKG,	
	user-supplied electrodes. Bio-potential	electrooculography (EOG) and		muscle tone, respiration effort-etc.	
	signals include: Electrocorticography	Evoked Potential (EP).		Signals are collected and processed	
	(ECoG), electroencephalography			as per traditional techniques of	
•	(EEG), electromyography (EMG),			EEG interpretation. Computer and	
	electrocardiography (ECG),			digital techniques enhance the	
	electrooculography (EOG) and Evoked			physician's capability of working	
	Potential (EP). Intended users include			with acquired trace data during the	
	Physicians, technicians, clinicians or			interpretation process.	
	other medical professionals that are			The system is a computer based	
-	trained in bio-potential and/or EEG			instrument for the acquisition,	
	recording			display, review and storage of	
	•			electromygraphic,	
				electroneurographic and evoked	
	The Cerveilo Ellie System does not			potential signals. The instrument	
	make any judgment of normality of		,	displays signals, aids in specific	
	abnormality of the displayed signals of			measurements but does not perform	
	the results of an analysis. In no way are			any interpretation or attempt to	`
	any of the functions represented as			evaluate any signals for their	
	being in and of themselves diagnostic.			pathologic relevance. All data	
				interpretation is performed by the	
				physician.	
	•			This submission covers only the	
				computer software used in the	
				system. It does not include any	
				hardware. It does not involve any	
-				patient monitoring or diagnosis.	
Intended Use	Bio-potential signal amplification,	Bio-potential signal amplification, recording,	Acquire, display, store, and	Acquisition, display and storage of	Same/equivalent intended use.
	recording, display, digitization,	display, digitization, retrieval and display.	archive electroencephalographic	biologic signals relating principally	Therefore, Substantially
	retrieval and display.		signals from the brain using a full	to cortical surface potentials with	Equivalent
			montage array (i.e., 16 or more	additional capabilities of collecting	
-			electrodes) and user-specified	polygraphic signals such as EKG,	
			locations.	musc letone, respiration effort etc.	
Intended User	Physicians, technicians, clinicians or other medical professionals that are	Trained clinicians working in research institutions, clinics, hospitals, operating	Physicians, technicians, or other medical professionals that are	Qualified personnel (doctors or technicians of the Neuro-	Same/equivalent intended users. Therefore, Substantially
•	trained in bio-potential recording	rooms, epilepsy evaluation unit	trained in EEG and/or PSG	physiopathological departments)	Equivalent
				}	Dogs & of 12

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	Ta	Table 4.0 Predicate Table Comparison -	ble Comparison	ı - Elite	
Feature	Blackrock NeuroMed Cervello Elite	Blackrock Neuroport Bio-potential Signal Processing System (K090957)	Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
		environments, sleep laboratories.	,		
Intended Use Environment	Clinics, hospitals, operating rooms,	Research institution, clinic, hospital,	Medical facility, physician's	Medical facilities	Same/equivalent clinical
	sleep laboratories.	environments, sleep laboratory.	onney, account y, came of annusing home of a medical facility under supervision of a medical arcfaceinal		Therefore, Substantially Equivalent
Target Patient	Adults and nediatrics	Not stated	The device will be available on all	Not stated	Same/equivalent patient
Population			patient populations as determined		populations,
			by a trained professional		Therefore, Substantially Equivalent
Use limitations	The System is not a monitoring system.	The System is not a monitoring system. No	These devices do not provide	[The device] does not involve any	Same/equivalent use limitations.
	The acquisition and display of bio-	physiologic at a first province, the acquisition and display of bio-potential	as an automated apnea monitor.	patient monitoring of diagnosis	Equivalent
	potential signals is for the interpretation	signals is for the interpretation and use of the	The devices do not make any		
	and use of the climbian. The devices control make any judgment of normality or abnormality of the displayed signals.	ÇIIIVLEII.	abnormality of the displayed signals.		
Bio-Potential	(Electroencephalography (EEG)	Electroencephalography (EEG) Electro-	Electroencephalography (EEG)	Polygraphic signals such as EKG,	Same/equivalent bio-potential
Signals Recorded	Electro-corticography (ECoG) Electrocardiography (ECG) Electro-	солісоgraphy (ECoG) Electrocardiography (ECG) Electro-myography (EMG)	Electrocardiography (ECG), Video EEG, Respiration, Heart	muscle tone, respiration effort-etc. and electromygraphic,	recordings. Therefore, Substantially
•	myography (EMG) Electrooculography	Electrooculography (EOG) Evoked potential	Rate, SPO,	electroneurographic and evoked	Equivalent
	(EOG) Evoked potential (Er), video EEG, Respiration, Heart rate, SPO <sub>2</sub>	(EF)		potentiai signais	
Clinical	Bio-potential signal amplification,	Bio-potential signal amplification, recording,	The device function is the	The System 98 software is intended	Same/equivalent clinical
Applications	recording, display, digitization, retrieval and display.	display, digitization, retrieval and display.	acquisition of bloelectric signals, as is typical for EEG amplifiers	to be used to perform neurophysiological exams such as	appucations. Therefore, Substantially
			and holster recorders.	EEG, EMG and EP	Equivalent
Number of	Up to 128 with one device, Up to 256	Up to 128 with one device, Up to 256 by	32 channels ·	N/A	Equivalent number of channels
Signal Recording Channels	by cascading two NeuroPort Bio- potential devices	cascading two devices			obtained via daisy-chaining. Therefore, Substantially
					Equivalent
Anafog Input Channels (per		.16	24	N/A	Same/equivalent number of analog channels per unit
unit)					Therefore, Substantially
A manife or family	1000 Macchin	1000 Moscolum	CINO COLES CARDO COL		Equivalent
Ampilier input	Loop Meganni	1000 Integonin	710 12 (dill), 73° 108 12 (CIVILI)	WW.	Collectivety, Identical to
mpedance					Substantially Equivalent
Amplifier DC	+ 500 mV	+ 500 mV	1V (15μV/digit)	N/A	Collectively, identical to
Signal Kange					predicates; therefore, Substantially Equivalent
Amplifier	0.3 to 7.5 kHz	0.3 to 7.5 kHz	0.15 – 220 Hz	V/N	Collectively, identical to
Response					Substantially Equivalent
A/D Conversion	16 bit	16 bit	16 bit	N/A	Collectively, identical to



	Ta	Table 4.0 Predicate Table Comparison - Elite	ble Comparison	- Elite	
Feature	Blackrock NeuroMed Cervello Elite	Blackrock Neuroport Bio-potential Signal Processing System (K090957)	Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
					predicates; therefore, Substantially Equivalent
Sampling Rate	Up to 30,000 Hz	Up to 30,000 Hz	8192 Hz per channel	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
CMRR	> 90 dB	> 90 dB	>100dB@201iz between G1 and all other inputs	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
Noise	< 3 µVrms	< 3 µVrms	<0.5μV r.m.s.@256Hz sampling rate	N/A	Collectively, identical to predicates, therefore, Substantially Equivalent
Power Source	120 VAC	120 VAC	2x 1,5V DC AA, alkaline batteries	120 VAC	Collectively, identical to predicates, therefore, Substantially Equivalent
Software	Cervello and Central	Central	Equivalent to Cervello	Equivalent to Cervello	Uses same software as the predicate devices; therefore substantially equivalent
Video Camera	Available	Not Stated	Available	Available	Uses same video canera running through the Cervello software: therefore substantially equivalent
Alarms	No	No	No	No	Collectively, identical to predicates, therefore, Substantially Equivalent
Operating System	Windows XP, 7, Server 2008 R2, Dual Core 2 GHz Processor	Windows XP	N/A	Windows, 150 MHz	PC Environment updated per new standard operating systems; therefore, Substantially Equivalent
Safety Standards Compliance	IEC 60601-1:1998 IEC 60601-1-2:2007 IEC 60601-2-26: 2002	HEC 60601-1:1998 HEC 60601-1-2:2001 HEC 60601-2-26	IEC 60601-1 (1988)+ A1:1991 + A2:1995 (2nd edition); IEC 60601-1-1 2000-12; IEC 60601-1-2:2001-09; IEC 60601-2-26:2002-11; IEC 60601-	N/A	Same/equivalent safety standards, Therefore, Substantially Equivalent



Blackrock NeuroMed Cervello Basic (Up to 64 channels with one Cervello Supports	Blackrock Neuroport Bio-potential	Micromed Mornhous atc	Airean Cornaration	Substantial Equivalence
_	Signal Processing System (K090957) Reference	Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
e e atc dical dical cor or cor cing	Supports recording, processing and display of biopotential signals from user supplied electrodes. Biopotential biopotential signals include: Electrocorticography (ECoC), electroencephalography (ECoC), electromyography (EMG), electrocardiography (EOC), electrocardiography (EOC), electrocoulography (EOC), electrocoulography (EOC), electrocoulography (EOC) and Evoked Potential (EP).	Acquire and store physiological signals for EtG and Sleep Studies, and to transfer the data to separate polysomnographic analysis software.	DA VINCHI EEG Systems are used for the acquisition, display and storage of biologic signals relating principally to, cortical surface potentials with additional capabilities of collecting polygraphic signals such as EKG, muscle tone, respiration effort-etc. Signals are collected and processed as per traditional techniques of EEG interpretation.  Computer and digital techniques enhance the physician's capability of working with acquired trace data during the interpretation process.  The system is a computer based instrument for the acquisition, display, review and storage of electromygraphic, eiectroneurographic and evoked potential signals. The instrument displays signals aids in specific measurements but does not perform any interpretation or attempt to evaluate any signals for their pathologic relevance. All data interpretation is performed by the physician.  This submission covers only the computer software used in the system. It does not include any hardware. It does not include any patient monitoring or diagnosis.	Same/equivalent intended use. Therefore, Substantially Equivalent
Acquire, display, store, and archive Bio-poter electroencephalographic signals from the recording brain using a full montage array (i.e., 16 retrieval a or more electrodes) and user-specified locations.	Bio-potential signal amplification, recording, display, digitization, retrieval and display.	Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array (i.e., 16 or more electrodes) and user-specified locations.	Acquisition, display and storage of biologic signals relating principally to cortical surface potentials with additional capabilities of collecting polygraphic signals such as EKG, muscletone, respiration effort etc.	Same/equivalent intended use. Identical to K071782. Therefore, Substantially Equivalent
Physicians, technicians, or other medical Trained c professionals that are trained in EEG institution and/or PSG rooms, eq environm	Trained clinicians working in research institutions, clinics, hospitals, operating rooms, epilepsy evaluation unit environments, sleep laboratories.	Physicians, technicians, or other medical professionals that are trained in EEG and/or PSG	Qualified personnel (doctors or technicians of the Neuro-physiopathological departments)	Same/equivalent intended users. Identical to K071782. Therefore, Substantially Equivalent
Medical facility, physician's office, laboratory, clinic or nursing home or operating outside of a medical facility under unit envisupervision of a medical professional	Research institution, clinic, hospital, operating room, epilepsy evaluation unit environments, sleep laboratory.	Medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under supervision of a medical professional	Medical facilities	Same/equivalent clinical environments. Identical to K071782. Therefore, Substantially Equivalent
The device will be available on all Not stated patient populations as determined by a	p	The device will be available on all patient populations as determined	Not stated	Same/equivalent patient populations. Identical to Page 8 of 13



		Table 4.0 Predicate T	4.0 Predicate Table Comparison - Basic	- Basic	
Feature	Blackrock NeuroMed Cervello Basic	Blackrock Neuroport Bio-potential Signal Processing System (K090957) Reference	Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
	trained professional		by a trained professional		K071782. Therefore, Substantially Equivalent
Use limitations	The System is not a monitoring system. No physiologic alarms are provided. The acquisition and display of bio-potential signals is for the interpretation and use of the clinician. The devices do not make any judgment of normality or abnormality of the displayed signals.	The System is not a monitoring system.  No physiologic alarms are provided.  The acquisition and display of biopotential signals is for the interpretation and use of the clinician.	These devices do not provide alarms and is not intended for use as an automated apnea monitor. The devices do not make any judgment of normality or abnormality of the displayed signals.	(The device) does not involve any patient monitoring or diagnosis	Same/equivalent use limitations. Therefore, Substantially Equivalent
Bio-Potential Signals Recorded	Electroencephalography (EEG), Video EEG, Respiration, Heart Rate, SPO <sub>2</sub>	Electroencephalography (EEG) Electro- corlicography (ECoG) Electrocardiography (ECG) Electro- myography (EMG) Electrooculography (EOG) Evoked potential (EP)	Electroencephalography (EEG) Electrocardiography (ECG) Video EEG, Respiration, Heart Rate, SPO <sub>2</sub>	Polygraphic signals such as EKG, muscle tone, respiration effort-etc. and electromygraphic, ejectroneurographic and evoked potential signals	Same/equivalent bio-potential recordings. Therefore, Substantially Equivalent
Clinical Applications	Acquisition of bio-electrical signals including EEG and Video EEG recording.	Bio-potential signal amplification, recording, display, digitization, retrieval and display.	The device function is the acquisition of bioelectric signals, as is typical for EEG amplifiers and holster recorders.	The System 98 software is intended to be used to perform neurophysiological exams such as EEG, EMG and EP	Same/equivalent clinical applications. Therefore, Substantially Equivalent
Number of Signal Recording Channels	64 channels with one device. 128 channels by cascading two devices	Up to 128 with one device; Up to 256 by cascading two devices	32 channels	N/A	Equivalent number of channels obtained via daisy-chaining. Therefore, Substantially Equivalent
Analog Input Channels (per unit)	24 per unit		24	N/A	Same/equivalent number of analog channels per unit. Therefore, Substantially Equivalent
Ampliffer Input Impedance	>10³ Ω (diff); >5*108 Ω (CMII)	1000 Megohm	>10³Ω (diff);>5*108Ω (CMII)	N/A	Same/equivalent number of analog channels per unit. Identical to K071782. Therefore, Substantially Equivalent
Amplifier DC Signal Range	1V (1SµV/digit)	+ 500 mV	1V (15μV/digit)	N/A ,	Collectively, identical to predicates; therefore, Substantially Equivalent
Amplifier Frequency Response	0.15 <b>–</b> 220 Hz	0.3 to 7.5 kHz	0.15 – 220 Hz	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
A/D Conversion	16 bit	16 bit ·	16 bit	N/A	Collectively, identical to predicates, therefore, Substantially Equivalent
Sampling Rate	8192 Hz per channel	Up to 30,000 Hz	8192 Hz per channel	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
CMRR	>100dB@20Hz between G1 and all other	> 90 dB	>100dB@20Hz between G1 and	N/A	Collectively, identical to

	L	Table 4.0 Predicate T	4.0 Predicate Table Comparison - Basic	- Basic	
		Blackrock Neuroport Bio-potential	b.	The state of the s	
Kooture	Blocknock NeuroMed Cercello Bosic	Signal Processing System (K000957) Reference	Micromed Morpheus, etc. (K671782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
	inputs		all other inputs		predicates, therefore,
	-		•		Substantially Equivalent
Noise	<0.5μV r.m.s.@256Hz sampling rate	< 3 µVrms	<0.5μV r.m.s.@256Hz sampling	N/A	Collectively, identical to
	)		rate		predicates; therefore,
					Substantially Equivalent
Power Source	Acquisition unit, 2x 1,5V DC AA,	120 VAC	2x 1,5V DC AA, alkaline	120 VAC	Collectively, identical to
•	alkaline batteries, computer (for		batteries		predicates, therefore,
	software), 120 VAC				Substantially Equivalent
Software	Cervello	Central	Equivalent to Cervello	Equivalent to Cervello	Collectively, identical to
					predicates; therefore,
					Substantially Equivalent
Video Camera	Available	Not Stated	Available	Available	Uses same software as the
					predicate devices; therefore
					substantially equivalent
Alarms	No	No	No	No	Uses same video camera
					running through the Cervello
					software; therefore
					substantially equivalent
Operating	Windows XP, 7, Server 2008 R2, , Dual	Windows XP	V/N	Windows, 150 MHz	PC Environment updated per
System	Core 2 GHz Processor				new standard operating
					systems; therefore,
					Substantially Equivalent
Safety Standards		IEC 60601-1;1998	IEC 60601-1 (1988)+ A1:1991 +	V/V	Same/equivalent safety
Compliance		IEC 60601-1-2:2001	A2:1995 (2nd edition); IEC		standards.
	IEC 60601-2-26; 2002	IEC 60601-2-26	60601-1-1 2000-12;		Therefore, Substantially
			IEC 60601-1-2:2001-09; IEC		Equivalent
			60601-2-26:2002-11; IEC 60601-		
			1-2,2001-09		



Ç#	Tabl	Table 4.0 Predicate Tabl	Predicate Table Comparison - Ambulatory	mbulatory	
Feature	k NeuroMed Cervi	13 27 5	Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
Indications for Use	Up to 64 channels with one Cervello hardware device (Amplifier) using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG.  The Cervello Ambulatory system does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.	Supports recording, processing and display of biopotential signals from user supplied electrodes. Biopotential signals include: Electroconicography (EEG), electromyography (EEG), electromyography (EMG), electrocoulography (EOG), electrocoulography (EOG), electrocoulography (EOG) and Evoked Potential (EP).	Acquire and store physiological signals for EEG and Sleep Studies, and to transfor the data to separate polysonnographic analysis software.	DA VINCHI EEG Systems are used for the acquisition, display and storage of biologic signals relating principally to, cortical surface potentials with additional capabilities of collecting polygraphic signals such as EKG, muscle tone, respiration offort-etc. Signals are collected and processed as per traditional techniques of EEG interpretation.  Computer and 'digital techniques enhance the physician's capability of working with acquired trace data during the interpretation process.  The system is a computer based instrument for the acquisition, display, review and storage of electromygraphic, electromeurographic and evoked potential signals. The instrument displays signals, aids in specific measurements but does not perform any interpretation or attempt to evaluate any signals for their pathologic relevance. All data interpretation is performed by the physician.  This submission covers only the computer software used in the system. It does not include any hardware.	Samc/equivalent indications for Use. Therefore, Substantially Equivalent.
Intended Use	Acquire, display, store, and archive electroencephalographic signals from the brain	Bio-potential signal amplification, recording, display, digitization, retrieval and display.	Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array (i.e., 16 or more electrodes) and user-specified locations.	Acquisition, display and storage of biologic signals relating principally to cortical surface potentials with additional capabilities of collecting polygraphic signals such as EKG, muscletone, respiration effort etc.	Same/equivalent intended use. Therefore, Substantially Equivalent
Intended User	Physicians, technicians, or other medical professionals that are trained in EEG and/or PSG	Trained clinicians working in research institutions, clinics, hospitals, operating rooms, epilepsy evaluation unit environments, sleep laboratories.	Physicians, technicians, or other medical professionals that are trained in EEG and/or PSG	Qualified personnel (doctors or technicians of the Neurophysiopathological departments)	Same/equivalent intended users. Identical to K071782. Therefore, Substantially Iquivalent
Intended Use Environment	Medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under supervision of a medical professional	Research institution, clinic, hospital, operating room, cpilepsy evaluation unit environments, sleep laboratory.	Medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under supervision of a medical professional	Medical facilities	Same/equivalent clinical environments. Identical to K071782. Therefore, Substantially Equivalent
Target Patient Population	The device will be available on all patient populations as determined by a	The device will be available on all patient populations as determined by a	The device will be available on all patient populations as determined	Not stated ·	Same/equivalent patient populations. Identical to

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	Table 4:0	1 6	Predicate Table Comparison - Ambulatory	mbulatory	
Reature	Blackrock NeuroMed Cervello	Blackrock Neuroport Bio-potential Signal Processing System (K090957):Reference	: Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence
	trained professional	trained professional	by a trained professional		K071782. Therefore, Substantially Equivalent
Use limitations	The System is not a monitoring system. No physiologic alarms are provided. The acquisition and display of bio-potential signals is for the interpretation and use of the clinician. The devices do not make any judgment of normality or abnormality of the displayed signals.	The System is not a monitoring system.  No physiologic alarms are provided.  The acquisition and display of biopotential signals is for the interpretation and use of the clinician.	These devices do not provide alarms and is not intended for use as an automated apnea monitor. The devices do not make any judgment of normality or abnormality of the displayed signals.	[The device] does not involve any patient monitoring or diagnosis	Same/equivalent use limitations. Therefore, Substantially Equivalent
Bio-Potential Signals Recorded	Electroencephalography (EEG) , Respiration, Heart Rate, SPO <sub>2</sub>	Electroencephalography (EEG) Electro- corticography (ECoG) Electrocardiography (ECG) Electro- myography (EMG) Electrooculography (EOG) Evoked potential (EP)	Electroencephalography (EEG) , Respiration, Heart Rate, SPO <sub>2</sub>	Polygraphic signals such as EKG, muscle tone, respiration effort-etc. and electromygraphic, eiectroneurographic and evoked potential signals	Same/equivalent bio-potential recordings. Identical to K071782. Therefore, Substantially Equivalent
Clinical Applications	The acquistion of bioelectric signals, as is typical for EEG amplifiers	Bio-potential signal amplification, recording, display, digitization, retrieval and display.	The device function is the acquisition of bioelectric signals, as is typical for EEG amplifiers and holster recorders.	Intended to be used to perform neurophysiological exams such as EEG	Same/equivalent clinical applications. Therefore, Substantially Equivalent
Number of Signal Recording Channels	64 channels with one device.	Up to 128 with one device; Up to 256 by cascading two devices	32 channels	N/A	Equivalent number of channels obtained via daisy-chaining. Therefore, Substantially Equivalent
Analog Input Channels (per unit)	24 per unit		24	N/A	Same/equivalent number of analog channels per unit. Identical to K071/782. Therefore, Substantially Equivalent
Amplifier Input Impedance	>10° Ω (diff); >5*108 Ω (CMII)	1000 Megohm	>10³Ω (diff); >5*108Ω (CMII)	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
Amplifier DC Signal Range	IV (15µV/digit)	. Am 005 +	ΙV (15μV/digit)	N/A	Collectively, identical to predicates, therefore, Substantially Equivalent
Amplifier Frequency Response	0.15 – 220 Hz	0.3 to 7.5 kHz	0.15 – 220 Hz	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
A/D Conversion	16 bit	16 bit	16 bit	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
Sampling Rate	8192 Hz per channel	Up to 30,000 Hz	8192 Hz per channel	N/A ·	Collectively, identical to predicates; therefore, Substantially Equivalent
CMRR	>100dB@20Hz between G1 and all other inputs	. Substitution of the subs	>100dB@20Hz between G1 and all other inputs	N/A	Collectively, identical to predicates; therefore,



:	Tab]	Table 4.0 Predicate Tabl	Predicate Table Comparison - Ambulatory	mbulatory	
	Blackrock NeuroMed Cervello	Blackrock Neuroport Bio-potential Signal Processing System	Micromed Morpheus, etc.	Airsep Corporation	Substantial Equivalence
Feature	Ambulatory	(K090957) Reference	(K0/1/82)	(K000963)	Comments Substantially Fourivalent
Moica	// S.W r m r (2)\$\$6.12 complete rate	< 3 uVrms	<0.5 til V r m s @256Hz samnling	N/A	Collectively identical to
Acion:	SOLDLY LITTLE (@2001E Samping rate	2	rate		predicates; therefore,
					Substantially Equivalent
Power Source	2x 1,5V DC AA, alkaline batteries	120 VAC	2x 1,5V DC AA, alkaline	120 VAC	Collectively, identical to
			batteries		predicates; therefore,
					Substantially Equivalent
Software	Cervello	Central	Equivalent to Cervello	Equivalent to Cervello	Uses same software as the
					predicate devices, therefore
					substantially equivalent
Video Camera	Available	Not Stated	Available	Available	Uses same video camera
					running through the Cervello
					software; therefore
					substantially equivalent
Alarms	No	No	No	No	Collectively, identical to
-					predicates; therefore,
					Substantially Equivalent
Operating	N/A	Windows XP	N/A	Windows, 150 MHz	PC Environment updated per
System					new standard operating
					systems; therefore,
					Substantially Equivalent
Safety Standards	IEC 60601-1:1998	IEC 60601-1:1998	TEC 60601-1 (1988)+ A1:1991 +	N/A	Same/equivalent safety
Compliance	IEC 60601-1-2:2007	IEC 60601-1-2:2001	A2:1995 (2nd edition); IEC		standards.
	IEC 60601-2-26: 2002	IEC 60601-2-26	60601-1-1 2000-12;		Therefore, Substantially
	·	w3	IEC 60601-1-2:2001-09; IEC		Equivalent
			60601-2-26:2002-11; IEC 60601-		
			60-1007:7-1		,

environment. In all cases, the devices are substantially equivalent and the same or better safety standards are met. In addition, no new issues of pertaining to Based on the predicate device comparison tables for the system under review, and the selected predicates, it is clear that these devices operate in an identical fashion, and there are no major deviations in design or functionality. The major differences in the systems pertain to allowing for different configurations of the hardware units, the potential for operating either hardware platform on either software platform, and a general upgrading of the computer operating biocompatibility have been raised and no clinical data was acquired.

# 14. Conclusions

The modifications to the Predicate Systems to create the Blackrock NeuroMed Cervello Elite, Cervello Basic and Cervello Ambulatory were evaluated and raise no new questions of safety or effectiveness.



May 02,2013

Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – W066-G609 Silver Spring, MD 20993-0002

Blackrock Neuromed, LLC. c/o John Ziobro SpectrMedex 117 West South Street Oconomowo, WI 53066

Re: K122196

Trade/Device Name: Cervello Bio-potential Signal Acquisition System Product Family:

Cervello Elite Cervello Basic

Cervello Ambulatory

Regulation Number: 21 CFR 882.1400 Regulation Name: Electroencephalograph

Regulatory Class: Class II

Product Code: GWQ, OLV, GWL, GWK

Dated: March 15, 2013 Received: April 4, 2013

Dear Mr. Ziobro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21)

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: <a href="http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm">http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm</a>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to:

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

# Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K122196

Device Name: Cervello Bio-Potential Signal Acquisition System

Indications For Use:

The Blackrock NeuroMed Cervello Bio-Potential Signal Acquisition Product Family contains the following configurations:

## **Ambulatory**

Up to 64 channels with one Cervello hardware device (Amplifier) using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG.

The Cervello Ambulatory System does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

## Basic

Up to 64 channels with one Cervello hardware device (Amplifier) and up to 128 channels by cascading 2 Cervello devices using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG.

The Cervello Basic System does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

## Elite

Up to 128 with one Neuroport Bio-Potential Recording Systems and up to 256 by cascading two Neuroport systems using the Central and/or Cervello software. The system supports recording, processing and display of bio-potential signals from user-supplied electrodes. Bio-potential signals include: Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG), electrooculography (EOG) and Evoked Potential (EP). Intended users include Physicians, technicians, clinicians or other medical professionals that are trained in bio-potential and/or EEG recording.

The Cervello Elite System does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

Prescription Use X AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

## Joyce MWhang -S

(Division Sign Off)

Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number <u>K122196</u>